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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,217	03/30/2005	Yusuke Nakamura	082368-003910US	1888

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EXAMINER	
WOLLENBERGER, LOUIS V	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,217

Applicant(s)

NAKAMURA ET AL.

Examiner

Louis V. Wollenberger

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 11-18, 20, 24, 27-30 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 8-10, 19, 21-23, 25, 26 and 31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1635

DETAILED ACTION

DETAILED ACTION

Location of the Application

The location of the application has changed. The application is now located in Art Unit 1635 and has been docketed to Examiner Louis Wollenberger.

Election/Amendments/Status

Applicant's election without traverse of Group IV, claims 8-10, 19, 21-23, 25, 26 and 31 in the reply filed on 5/24/2007 is acknowledged.

Also acknowledged, are Applicants' amendments to the claims.

With entry of the amendment, claims 1-32 are pending. Claims 1-7, 11-18, 20, 24, 27-30, and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/24/07.

Claims 8-10, 19, 21-23, 25, 26 and 31 are subject to further restriction, as explained below, as the claims are not considered to be drawn to a single inventive concept under PCT Rule 13.1.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Art Unit: 1635

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 8, 9, 19, and 22, drawn to an antisense polynucleotide and composition thereof targeted to a polypeptide comprising the amino acid sequence of SEQ ID NO: 16.

Group II, claim(s) 8, 9, 19, and 22, drawn to an antisense polynucleotide and composition thereof targeted to a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16 in which one or more amino acids are substituted, deleted, inserted, and/or added.

Group III, claim(s) 8, 9, 19, and 22, drawn to an antisense polynucleotide and composition thereof targeted to a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

Group IV, claim(s) 8, 10, 19, and 22, drawn to a small interfering RNA and composition thereof targeted to a polypeptide comprising the amino acid sequence of SEQ ID NO: 16.

Group V, claim(s) 8, 10, 19, and 22, drawn to a small interfering RNA and composition thereof targeted to a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16 in which one or more amino acids are substituted, deleted, inserted, and/or added.

Group VI, claim(s) 8, 10, 19, and 22, drawn to a small interfering RNA and composition thereof targeted to a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

Group VII, claim(s) 21 and 31, drawn to a composition comprising a compound for treating a cell proliferative disease, said compound selected by one of the methods of claims 13 to 17.

Group VIII, claim(s) 23 and 26, drawn to a method for treating a cell proliferative disease comprising administering a pharmaceutically effective amount of an antisense polynucleotide targeted to a polypeptide comprising the amino acid sequence of SEQ ID NO: 16.

Art Unit: 1635

Group IX, claim(s) 23 and 26, drawn to a method for treating a cell proliferative disease comprising administering a pharmaceutically effective amount of an antisense polynucleotide targeted to a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16 in which one or more amino acids are substituted, deleted, inserted, and/or added.

Group X, claim(s) 23 and 26, drawn to a method for treating a cell proliferative disease comprising administering a pharmaceutically effective amount of an antisense polynucleotide targeted to a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

Group XI, claim(s) 23 and 26, drawn to a method for treating a cell proliferative disease comprising administering a pharmaceutically effective amount of a small interfering RNA targeted to a polypeptide comprising the amino acid sequence of SEQ ID NO: 16.

Group XII, claim(s) 23 and 26, drawn to a method for treating a cell proliferative disease comprising administering a pharmaceutically effective amount of a small interfering RNA targeted to a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16 in which one or more amino acids are substituted, deleted, inserted, and/or added.

Group XIII, claim(s) 23 and 26, drawn to a method for treating a cell proliferative disease comprising administering a pharmaceutically effective amount of a small interfering RNA targeted to a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

Group XIV, claim(s) 25, drawn to a method for treating a cell proliferative disease comprising administering a pharmaceutically effective amount of a compound selected by the screening method recited therein.

The inventions listed as Groups I–XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical feature of Groups I–III and VIII–X is an antisense polynucleotide, which is not present or specifically required by any of the other groups.

The special technical feature of Groups IV–VI and XI–XIII is a small interfering RNA, which is not present or specifically required by any of the other groups.

Art Unit: 1635

The special technical feature of Groups VII and XIV is a compound selected by one of the screening methods recited in claims 13-17 and 25, which methods embrace screening a wide variety of test and candidate compounds having unknown inhibitory profiles, which may result in the selection of any inorganic or organic, small or large molecule, protein, antibody, polynucleotide, polysaccharide, lipid, or steroid, for example, including such compounds that are neither present nor embraced by any of the other groups.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of Group I is an antisense polynucleotide targeted to a polypeptide comprising the amino acid sequence of SEQ ID NO: 16, which is neither present in nor specifically required by Groups II or III. Similarly, Groups II and III require an antisense polynucleotide targeted to a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16 in which one or more amino acids are substituted, deleted, inserted, and/or added, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15, respectively, which features are neither present in nor required by the other or by Group I. For the same reasons, the inventions listed as Groups VIII-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features, nor do Groups IV-VI or XI-XIII, since the target populations are structurally distinct, requiring structurally distinct small interfering RNAs and antisense polynucleotides, respectively.

With regard to Groups I-III as compared to VIII-X, and Groups IV-VI as compared to XI-XIII, the inventions do not relate to a single general inventive concept under PCT Rule 13.1 because the special technical feature of Groups VIII-X and XI-XIII is the treatment of a cell proliferative disease, specifically cancer, requiring administering either an antisense polynucleotide or small interfering RNA to a living subject afflicted with such a disease, which step may involve any of the modes of delivery described at page 33 of the specification, which features and steps are not specifically present in nor required by Groups I-III or IV-VI. Similar reasoning may be applied to Group VII as compared to Group XIV, not to mention that the different Groups may result in the selection of different compounds depending on the test compounds screened and the particular targets and methods used to screen them.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

Art Unit: 1635

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LW

Art Unit 1635

July 10, 2007

/Sean McGarry/
Primary Examiner
AU 1635